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PATENT APPLICATION
 Docket No.: 09751005-016

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Junming J.e, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight
 and Scott Siegel

Serial No.: 10/044,534

Group Art Unit: 1644

Filed: January 10, 2002

Examiner: Not assigned

For: METHODS OF TREATING ANKYLOSIS WITH CHIMERIC
 ANTI-TNF ANTIBODIES

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PETITION UNDER 37 C.F.R. §§1.181-1.183

Director of Technology Center 3640
 Washington, D.C. 20231

Sir:

This Petition is being submitted, *inter alia*, under 37 C.F.R. §1.181, in response to the decision mailed from the Patent Office on August 8, 2002, denying the Request for Reconsideration filed by applicants on June 26, 2002. The Petition is timely as it is being submitted within two months of the date of the decision. 37 C.F.R. §1.181(f). The Request for Reconsideration was filed in response to an informal notice of requirement for a Property Rights Statement for the above-referenced application. This Petition is submitted to the Director of Technology Center 3640 in compliance with MPEP 1002.02(c)(1). The formal 30-day notice of Requirement for Statement under

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FACSIMILE COVER SHEET

Examiner: Joanne P. Hodge
Supervisory Applications Examiner

Group: 1644

Date: September 20, 2002

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From: Carolyn Elmore

Subject: Paper: Petition Under 37 C.F.R. §§1.181-1.183

Docket No.: 0975.1005-016

Applicants: Junming Le, Jan Vilcek, Peter Daddona, John Ghayeb, David M.
Knight, Scott Siegel

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§ 152 of the Atomic Energy Act was issued from the Patent Office on September 6, 2002. Applicants have 30 days from that date to comply with the notice. Therefore, a prompt decision on this Petition is requested.

INTRODUCTION

This Petition is a combined Petition:

- (1) to withdraw the requirement for a property rights statement for this application;
- (2) to suspend the due date for filing the property rights statement pending resolution of said petition for said property rights statement requirement;
- (3) to waive the requirement of execution of the property rights statement by all of the inventors, should the property rights statement requirement not be withdrawn in its entirety; and
- (4) to permit a copy of one executed property rights statement to be filed in each related divisional application, should the property rights statement requirement not be withdrawn in its entirety.

- I. The property rights statement requirement for this application should be withdrawn because it is not contemplated by the statute and because the requirement would be unduly burdensome and prejudicial to the assignee.
- A. Patents merely disclosing the use of a radiolabeled probe in a working example are not encompassed in the requirements of 42 U.S.C. § 2182.

Applicants' Request for Reconsideration was denied on the grounds that a "review of the application file history reveals among other things the use of a radioactive isotope ¹²⁵I", as disclosed in at least page 11 of the instant specification". According to the Examiner, the application has been made available to the Department of Energy under 42 U.S.C. § 2182 on the grounds that the subject matter relates to at

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least G (Materials, apparatus and methods concerning isotope and/or radioactive source technology including those utilizing (including responsive to) radioactive sources); or H (Instruments employing a radioactive source and/or radioactivity detector in the operation thereof). Applicants hereby petition under 37 C.F.R. § 1.181 to have the requirement withdrawn.

The subject patent application teaches and claims, *inter alia*, specific antibodies and methods of treating infection and other diseases by administering antibodies against a cytokine known as tumor necrosis factor alpha (TNF α). The specification describes certain methods used in preparing the antibodies of the invention and certain methods related to testing, characterizing and screening the antibodies. The portion of the Specification cited by the Examiner as relevant to the property rights statement requirement refers to Figures 10A and 10B, which are described in Example X, "Specificity of an Anti-TNF Chimeric Antibody". This example used ^{125}I to label antibodies of the invention to determine their affinity of binding to TNF α . As such, the cited radioisotope was used merely as a research tool in the assessment of an antibody of the invention. The radioisotope is a well-known, commercially available research tool, routinely employed in biotechnology. The inventions described in this application in no way relate substantively to the radiolabel or its use. The disclosure of this radiolabel is merely incidental to the inventions disclosed and claimed in the application.

The purposes and statutory scheme of Section 2182 establish that patent applications of the nature of applicants' invention were not intended to be included in the requirements of this section. Parts G and H, cited by the Examiner, are not parts of Section 2182, nor do they appear anywhere in the statutory subchapter ("Patents and Inventions) of which it is a section.

The goals of Chapter 23 (of which Section 2182 is a part) include a program for Government control of the possession, use, and production of atomic energy and special nuclear material, whether owned by the Government or others, so directed as *to make the maximum contribution to the common defense and security and the national welfare, and to provide continued assurance of the Government's ability to enter into and enforce agreements with nations or groups of nations for the control of special nuclear*

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materials and atomic weapons (42 U.S.C. § 2013). This has nothing to do whatsoever with the use of commercially available, routine research tools such as the radiolabel used in the example described in this application. The use of a radiolabel to screen for the presence of an antibody gene in no way relates to "the common defense and security and the national welfare" of the US Government or inhibits "the Government's ability to enter into and enforce agreements with nations or groups of nations for the control of special nuclear materials and atomic weapons."

Similarly, cited Section 2182 reads in part:

No patent for any invention or discovery, useful in the production or utilization of special nuclear material or atomic energy, shall be issued unless the applicant files . . . a statement under oath setting forth the full facts surrounding the making or conception of the invention or discovery described in the application and whether the invention or discovery was made or conceived in the course of or under any contract, subcontract, or arrangement entered into with or for the benefit of the Commission . . .

Like Section 2013, Section 2182 refers to patents *for* inventions and discoveries which are "useful" in the "utilization" of radioactive substances. This patent application clearly does not fall within this category. The inventions and discoveries relate to novel antibodies and their uses in therapy and diagnostics. The statute does not require that all patent applications which merely make reference to a single use of such material, much less the use of a commercially available, routine research tool, are embraced. The mere observation that a radioisotope was used in some fashion in no way supports the allegation that the *inventions* described in the application are, *themselves*, useful in the utilization of radioactive material or for the common defense, national security or welfare of the Government.

The government's need to control inventions and discoveries regarding the production or utilization of special nuclear material or atomic energy will not be compromised if the PTO does not require executed properly rights statements of applicants for patents teaching antibodies and other therapeutics, or any other patent application which merely references the use of a radioactive label in a manner which is well known and routine. Applicants' invention is clearly not of primary importance in the production or utilization of special nuclear material or atomic energy, nor does it

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affect the common defense and security and the national welfare, nor does it affect continued assurance of the Government's ability to enter into and enforce agreements with nations or groups of nations for the control of special nuclear materials and atomic weapons (42 U.S.C. § 2013). As such, the request for a property rights statement in this application is not justified.

B. Requiring an executed property rights statement for every patent application that refers to using a radiolabel would be unduly burdensome.

Not only is a property rights statement not required in this technological context, such a requirement would put an enormous burden to the patent bar and the public in general and to the applicants of the subject application in particular.

A search of the patent office database at www.uspto.gov indicates that 2,317 issued patents containing the word "radiolabel" issued between 1996-2002. There are 4,154 patents containing the word "isotope" that issued over the same period. The word "radioactive" resulted in 19,065 hits. In those patent applications which have been published 2001 and 2002 (the last 19 months), 4,709 applications use at least one of these words. It is difficult to fathom that property rights statements were, or should have been, required in each of these applications or patents. To require a statement in each application that merely mentions the term, without regard to its context or the inventions which are actually described, would create an overwhelming administrative burden on the patent office and on patent applicants. This is particularly true since, as described above, the vast majority of these applications employ these terms in a context which clearly distance them from the intent and scope of the statute.

The subject application claims the benefit of priority from an application filed in 1991. The application relates to the antibody sold under the trademark Remicade, or infliximab, which has substantial commercial value. All of the inventors have assigned their rights to their respective employers. Two of the six applicants have long left their assignee's employ, and/or are now employed by the potential competitors of the assignee. Requiring the execution of property rights declarations in an application, such

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as this, appears to require the assignee to disclose confidential information, relating to the existence of continuing applications and content of the subject matter currently being prosecuted, to individuals who have no right, title or interest in the subject application. Thus, it would be unduly burdensome for the assignees to have declarations executed for this and the related applications in this patent application family.

Creating such a needless burden for biotechnological, therapeutic and pharmaceutical applications does not advance, and is inconsistent with, the policies declared in Chapter 23, namely (a) the direction of the development, use, and control of atomic energy so as to make the maximum contribution to the general welfare, subject at all times to the paramount objective of making the maximum contribution to the common defense and security; and (b) the development, use, and control of atomic energy shall be directed so as to promote world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise (42 U.S.C. § 2011).

C. A property rights statement requirement for applicants' application amounts to an arbitrary and capricious change in rule-making in violation of the Administrative Procedure Act.

Applicants have filed a series of applications disclosing related subject matter since March of 1991. Five patents have issued from this family of applications, including a patent of which the subject application is a divisional application, containing an identical specification. Yet, the applicants have never been notified of a requirement to submit a property rights statement until now. Indeed, the undersigned has filed many patent applications having similar references to radiolabels which have not been subjected to this requirement. Therefore, this appears to be a change in PTO rule-making. 5 U.S.C. § 553 of the Administrative Procedure Act mandates that a general notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual

notice thereof in accordance with law. This rule-making change was never published in the Federal Register, and applicants were not provided with notice of a change in the law, nor were they provided with a right to provide comments regarding the law.

II. The due date for filing the property rights statement should be suspended pending resolution of said petition for said property rights statement requirement, to provide an opportunity for interpretation and potential revision of the rule.

Applicants hereby petition under 37 C.F.R. § 1.183 to withdraw the 30-day letter pending resolution of this petition. The formal 30-day notice of Requirement for Statement under § 152 of the Atomic Energy Act was issued from the Patent Office on September 6, 2002. Applicants have 30 days from that date to comply with the notice. The 30-day deadline is very short, and it would prejudice the ability of the applicants to seek interpretation of the rule by PTO. As stated above, the applicants have filed applications containing the cited disclosure and have never before been notified of a property rights statement requirement. Nor have the applicants been notified in a change in the property rights statement rule. This change was never published in the Federal Register, and applicants were not provided with notice of a change in the law, nor were they provided with a right to provide comments regarding the law. This lack of due process is in direct violation of the Administrative Procedure Act. Moreover, two of the inventors have left the employ of the assignees. Therefore, since applicants are under a very short deadline, they may be forced to provide confidential information to competing entities in order to comply with the formal notice.

It is important to notice that, while the 30 day deadline is set by statute and, therefore, cannot be extended pursuant to 37 C.F.R. 1.136(a), the date or time of issuance of the letter is not set by statute. Thus, the Commissioner has the authority to delay the issuance of the requirement.

III. The requirement of execution of the property rights statement by all of the inventors should be waived, if the property rights statement requirement is not withdrawn in its entirety.

In the event that the petition to withdraw the property rights statement for this application is not granted, applicants hereby petition for permission to submit the property rights statement without execution by all of the inventors. It is believed that this petition is proper under 37 C.F.R. § 1.183.

The Manual of Patent Examining Procedure (MPEP) provides that when an applicant is unavailable (e.g., deceased, incompetent, refuses to sign or cannot be reached), a property rights statement setting forth the information required by the statutes may be accepted from an officer or employee of the assignee who has sufficient knowledge of the facts (MPEP § 151). Where it is shown that one of the joint inventors is deceased or unavailable, a statement by all of the other inventors may be accepted (*Id.*).

As stated above, in the eleven years since the first application in this family has been filed, two of the six inventors (Scott Siegel and Peter Daddona) have left the employ of the assignee. These inventors now work for potential competitors, and these competitors are not entitled to confidential information regarding the current filing strategies of the patent owners. Requiring the owners to divulge this information is unnecessary and potentially detrimental to their business interests in this field. Such an unnecessary burden is inconsistent with the policies declared Chapter 23, including the goal of strengthening free competition in private enterprise (42 U.S.C. § 2011). Inventors Siegel and Daddona should, therefore, be considered unavailable inventors, and applicants should not be required to file a property rights statement executed by these inventors.

Applicants propose that, should a property rights declaration be required for this application, the four other inventors should be permitted to execute the statement on behalf of inventors Siegel and Daddona. This situation is analogous to the situation where a party qualified under 37 C.F.R. § 1.47 may sign an affidavit or declaration

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under 37 C.F.R. § 1.131 when some or all of the inventors are not available or not capable of joining in the filing of an application (MPEP § 715.04).

Alternatively, the owners of the subject application should be permitted to execute the property rights statement as true owners of interest under 37 C.F.R. § 3.73(b). This situation is analogous to the situation where an assignee or other party of interest may sign an affidavit or declaration under 37 C.F.R. § 1.131 when it is not possible to produce the affidavit or declaration of the inventor (MPEP § 715.04).

Submission of a property rights declaration without the signatures of Dr. Siegel and Dr. Daddona would violate neither the language nor the policy behind the statute. Section 2182 only requires an applicant to file "a statement under oath". Nowhere does the statute indicate that the statement must be signed by all of the inventors. The policy of the statute would be furthered because the owners and the other inventors of the invention claimed in this application are knowledgeable regarding "the full facts surrounding the making or conception of the invention or discovery described in the application and whether the invention or discovery was made or conceived in the course of or under any contract, subcontract, or arrangement entered into with or for the benefit of the Commission", and they are competent to prepare and execute a statement to that effect, as required by the statute.

IV. Applicants should be permitted to file copies of a single executed property rights statement in all related applications, if the property rights statement requirement is not withdrawn in its entirety.

In the event that the petition to withdraw the property rights statement for this application is not granted, applicants hereby petition under 37 C.F.R. § 1.182 to submit one copy of the executed property rights statement in each related application of similar disclosure in which a property rights statement is required. As stated above, obtaining an executed property rights statement for each and every subject application may be very burdensome and require disclosure of highly confidential information, depending upon which, if any, of the above petitions are granted. Currently, there are sixteen

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related applications, which are all divisional applications derived from the same parent, which is now an issued patent. It would be highly burdensome for the applicants to obtain signatures from all six inventors for all such divisional applications, as well as subsequently filed applications as may be required by the USPTO under 35 USC 121, for example. Moreover, it would not further the goals of the statute, because, for the purposes of the statute, the "full facts surrounding the making or conception of the invention or discovery described in the application and whether the invention or discovery was made or conceived in the course of or under any contract, subcontract, or arrangement entered into with or for the benefit of the Commission" will be the same for each application.

This practice would be similar to the well-accepted practice of allowing a patent applicant to utilize copies of an executed 35 U.S.C. § 115 declaration to satisfy the requirements for multiple applications for patents. Specifically, under 37 C.F.R. § 1.63(d), a newly executed oath or declaration is not required in a continuation or divisional application provided that: the prior application contained a duly executed oath or declaration; the continuation or divisional application was filed by all or fewer than all of the inventors named in the prior application; the continuation or divisional application contain no matter that would have been new matter in the prior application, and a copy of the executed oath or declaration filed in the parent application is submitted in the continuation or divisional application. If the first application in which a property rights statement is submitted is treated as the "prior application", the situation under 37 C.F.R. § 1.63(d) and the current situation are identical.

Please charge Deposit Account No. 08-0380 for any fees that may be due in this matter.

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CONCLUSION

Grant of the Petitions of Part I and II is respectfully requested. If the Petition of Part I is denied, grant of the Petitions of Parts III and IV is respectfully requested.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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